UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

VERAX BIOMEDICAL INC.,

Plaintiff,

v.

THE AMERICAN NATIONAL RED CROSS,

Defendant.

Civil Action No. _____

COMPLAINT

JURY TRIAL DEMANDED

I. NATURE OF THE ACTION

1. The antitrust laws apply to everyone, even the American National Red Cross ("ARC").

2. In the United States, ARC is synonymous with blood. ARC dominates the national blood products markets, including the market for platelets where it has a dominant national market share. Due to the chronic scarcity of platelets and their short shelf life, most hospitals rely on ARC—often predominantly and sometimes exclusively—to supply the platelets they desperately need for life-saving transfusions.

3. Platelets are a critical life-saving product used to help patients with cancer, blood disorders, critical injuries, and major surgeries.

4. Unfortunately, platelets are also susceptible to bacterial contamination, which can cause serious, even fatal, side effects in transfusion recipients. As a result, the U.S. Food and Drug Administration ("FDA") recommends that hospitals and blood centers mitigate the risk of bacterial contamination before transfusing platelets. The FDA has endorsed the safety and effectiveness of multiple platelet bacteria mitigation services, including pathogen reduction treatment, large volume delayed sampling, and secondary testing with a culture or rapid test.

5. Robust competition in the U.S. platelet bacteria mitigation services market is critical to the delivery and supply of safe, high quality, low priced platelet transfusions to critically ill and injured patients. The ready availability of multiple platelet bacteria mitigation service options is likewise critical to hospitals' ability to effectively manage their platelet inventories, minimize their costs, and offer their patients timely platelet transfusions.

6. Unfortunately, ARC has embarked on a campaign to illegally smother this robust competition and obtain a monopoly in the U.S. market for platelet bacteria mitigation services.

7. In July 2020, ARC announced that it intended to perform the pathogen reduction platelet bacteria mitigation service on all of the platelets it collects before it sells them to hospitals.

8. In other words, ARC declared that it will tie its sales of platelets to sales of its platelet bacteria mitigation service, thereby leveraging its dominant position in the U.S. platelet market to obtain a monopoly in the U.S. platelet bacteria mitigation services market.

9. As a result of this policy, ARC's platelet customers—many of whom rely predominantly or entirely on ARC for their supply of life-saving platelets—are being required to buy their platelet bacteria mitigation services only from ARC, rather than from their preferred seller.

10. ARC is charging its platelet customers $150 per platelet dose for its pathogen reduction service, while other sellers offer substitute platelet bacteria mitigation services for as little as $25 per dose.

11. Upon information and belief, many of ARC's customers buy all of their platelets from ARC and are therefore being coerced into *de facto* exclusive dealing agreements for their platelet bacteria mitigation services.

12. These exclusive dealing arrangements are foreclosing a substantial share of the U.S. market for platelet bacteria mitigation services.

13. ARC is unlawfully engaging in tying, exclusive dealing, and attempted monopolization in violation of the Sherman Act. Without judicial intervention, there is a substantial risk that ARC will unlawfully achieve a monopoly in the U.S. platelet bacteria mitigation services market.

14. Already, ARC's unlawful conduct is causing substantial harm to consumers in the form of higher prices, lower quality, increased waste, and loss of choice and innovation.

15. ARC's unlawful conduct is also exacerbating platelet shortages, which increases the risk that sick patients cannot get the transfusions they need when they need them.

16. Verax Biomedical Incorporated ("Verax") is the supplier of the FDA-cleared rapid test, PGD*prime*.

17. Verax's PGD*prime* competes against ARC's pathogen reduction treatment in the U.S. platelet bacteria mitigation services market.

18. ARC's illegal anticompetitive conduct is harming Verax by illegally foreclosing a substantial share of the U.S. platelet bacteria mitigation services market, which is increasing Verax's costs and reducing its revenue.

19. To further harm Verax, ARC has also engaged in numerous unfair methods of competition and unfair and deceptive trade practices, including defamation, false advertising, and tortious inference.

20. In particular, ARC has been intentionally publishing false statements about the efficacy, safety, and cost of Verax's PGD*prime* test and about ARC's own pathogen reduction treatment in an attempt to interfere with Verax's contractual relationships with its customers.

21. ARC's misconduct is directly and proximately causing Verax to suffer economic injury in the form of lost revenues and sales.

22. Verax brings this action against ARC to restore competition in the U.S. platelet bacteria mitigation services market and to enjoin ARC from suppressing that competition by leveraging its existing dominance over the separate U.S. platelet market.

II. JURISDICTION AND VENUE

23. This Court has subject matter jurisdiction over this lawsuit under 15 U.S.C. §§ 15, 26 and 28 U.S.C. §§ 1331, 1337, 1367.

24. This Court has personal jurisdiction over ARC because ARC has engaged in sufficient minimum contacts with the United States and Massachusetts and has purposefully availed itself of the benefits and protections of the United State and Massachusetts such that the exercise of jurisdiction over ARC would comport with due process requirements. ARC's business activities that are the subject of this Complaint are within the flow of, and substantially affect, interstate trade and commerce.

25. Venue is proper in this District under 28 U.S.C. § 1391(e) because a substantial portion of the events giving rise to this action occurred in this District.

III. PARTIES

26. Plaintiff Verax is a corporation organized and existing under the laws of Delaware, having its principal place of business in Marlborough, Massachusetts.

27. Verax is a medical products company dedicated to developing, validating, and commercializing FDA-cleared tests for detecting bacterial contamination in platelets intended for transfusion.

28. Defendant ARC is a non-profit institution that is organized and exists pursuant to a charter granted by the United States Congress, having its principal place of business in Washington, DC.

29. ARC collects, processes, and sells platelets throughout the United States, including in Massachusetts. ARC also sells platelet bacteria mitigation services throughout the United States, including in Massachusetts.

IV. FACTUAL ALLEGATIONS

A. The Red Cross Dominates the U.S. Market for Blood Platelets.

30. Platelets are the cell fragments in blood that bind together to form clots, which stop bleeding and repair damaged blood vessels.

31. Platelet transfusions are given to patients who do not have enough platelets of their own or whose own platelets are not working correctly. Platelet transfusions help patients survive traumatic injuries, major surgeries, cancers, and chronic diseases.

32. Some individuals, such as certain cancer patients, need recurring platelet transfusions because their illnesses prevent or reduce the formation of platelets or degrade the effectiveness of their platelets. For example, chemotherapy can damage bone marrow, thereby reducing platelet production. Certain autoimmune diseases, infections, medicines, and medical conditions can destroy platelets, necessitating platelet transfusions.

33. Platelets are collected from unpaid volunteer donors, usually through a "platelet only donation," where a donor's blood is processed through an apheresis machine, which extracts the platelets suspended in donor plasma and returns the other blood components to the donor.

34. Platelets are generally donated at "blood centers,"[1] such as those run by ARC. Blood centers collect platelets, process them, and then sell "doses" of them to hospitals.

35. The platelets collected from a single donor in a single sitting typically generate 1–3 platelet "doses." A "dose" of platelets is a single bag that can be transfused into a patient. The FDA has set guidelines for the minimum size of a dose, both in terms of the minimum number of platelets and the minimum amount of plasma in each bag.

36. Platelets collected from a donor can either be sold entirely in the donor's plasma, known as "plasma platelets," or the blood center can replace some of the plasma with Platelet Additive Solution ("PAS") and sell "PAS platelets."

[1] Blood centers—or "blood establishments" as the FDA calls them—are facilities equipped to collect, process, and distribute licensed blood products from donors.

37. Platelet donations are more intensive than other types of blood donations. Platelet donors are required to sit for an extended period of time, often about three hours.

38. The U.S. platelet market is severely supply constrained. There is a constant need for more platelet donations in the United States, with the number of patients needing platelet transfusions routinely outpacing the number of people donating platelets. Insufficient supply of platelets is a chronic problem for hospitals.

39. ARC is by far the largest supplier of platelets in the United States. ARC collects free donated platelets at its blood centers and then sells doses of platelets to hospitals at a profit.

40. By its own accounts, ARC supplies more than 40% of all platelets sold in the United States.

41. Upon information and belief, ARC supplies approximately half of all platelets in the United States and an even higher percentage of platelets in some regions of the United States.

42. Upon information and belief, ARC is the sole supplier of platelets to many hospitals and in some regions in the United States. These hospitals are entirely reliant on ARC for their patients' platelet needs.

43. The national platelet supply shortage has been greatly exacerbated over the past few years as a result of COIVD-19, which has caused an approximate 10% decline in platelet donations.

44. In January 2022, ARC declared a "national blood crisis" due to the massive shortage of platelets and other blood products.

B. The FDA Recommends the Use of Platelet Bacteria Mitigation Services.

45. While platelet transfusions are life-saving procedures, they are not without risks.

46. Platelets are highly susceptible to bacterial contamination, which can cause infections, sepsis, multi-organ failure, and death. According to the FDA, platelets are associated with a higher risk of sepsis and death than any other transfusable blood component.

47. As a result, the FDA has issued a regulation requiring blood centers to "assure that the risk of bacterial contamination of platelets is adequately controlled using FDA approved or cleared devices or other adequate and appropriate methods found acceptable for this purpose by FDA."[2]

48. Starting in 2004, the Association for the Advancement of Blood and Biotherapies ("AABB")—a standard-setting body for the blood products industry—required that all platelets be tested for bacterial contamination.

49. Blood centers, including the ARC, implemented a platelet bacteria mitigation service called a Primary Culture.

50. A Primary Culture involves placing a small sample of each platelet collection (before it is split into doses) in a culture bottle and then monitoring that bottle for the presence of carbon dioxide, which indicates the presence and growth of bacteria.

51. The Primary Culture is performed 24 hours after platelet collection, and the culture must be monitored for at least 12 hours before the platelets may be sold. As a result, Primary Cultured platelets cannot be sold to hospitals until at least 36 hours after they are collected.

52. Unfortunately, Primary Culturing by itself proved to be an inadequate platelet bacteria mitigation service for platelets that are transfused following Day 3 after collection (day of collection is Day 0). The FDA identified numerous such platelets that tested negative for bacterial

[2] 21 C.F.R. 606.145 (May 22, 2015).

contamination and were subsequently transfused into patients who experienced infection, sepsis, multi-organ failure, and even death.

53. In September 2019, the FDA issued guidance to blood centers endorsing several different platelet bacteria mitigation services that comply with 21 CFR 606.145(a). These services include Primary Culturing, pathogen reduction treatment ("PRT"), large volume delayed sampling ("LVDS") and secondary testing in combination with the Primary Culturing ("Secondary Testing").

54. The FDA's guidance was updated in December 2020 to extend the deadline for implementation of these FDA-endorsed platelet bacteria mitigation services to October 2021.

55. Since October 1, 2021, every single unit of platelets in the US must be subjected to at least one bacterial mitigation method.

C. The Three Primary Types of Platelet Bacteria Mitigation Services Offer Different Advantages and Disadvantages.

56. PRT, LVDS, and Secondary Testing are the three primary types of platelet bacteria mitigation services. The FDA recommends that blood centers and hospitals implement one or more of these options.

57. Primary Culturing is an FDA-approved platelet bacteria mitigation service, but it is rarely used (by itself) because it produces platelets that can only be transfused through Day 3 (per FDA Guidance).

58. PRT, LVDS, and Secondary Testing are substitute services. Together these three options make up the market for platelet bacteria mitigation services.

59. The FDA has expressed no preference among these three options and leaves it to each individual hospital to select the service(s) that best fits its particular needs and patient population.

60. PRT, LVDS, and Secondary Testing are all considered safe and effective, but they offer distinct trade-offs for hospitals and patients.

61. The AABB issued a bulletin explaining that while all three services are "supported by the FDA . . . each methodology will have some impact on platelet quality, dose, availability and other factors that could affect clinical utility."[3]

62. As a result, the AABB advises blood centers to offer and hospitals to accept multiple platelet bacteria mitigation services and always be prepared to perform Secondary Testing as a backstop.

1. Pathogen Reduction Treatment

63. PRT is the process of adding a chemical DNA cross-linker solution to a bag of platelets and then exposing the mixture to ultraviolet light to inhibit replication of bacterial organisms.

64. Cerus Corporation manufacturers the INTERCEPT Blood System, which is currently the only FDA-approved PRT available for platelets.

65. PRT is usually performed on platelets shortly after they are collected. The PRT process is performed instead of (not in addition to) the traditional Primary Culture.

66. The PRT process results in the loss of approximately 10–15% of the platelet product, compared to the Primary Culture, which results in the loss of 3–8% of the platelet product.

67. The PRT process degrades platelets, rendering them less efficacious. Thus, patients may need more PRT platelet doses to achieve the same therapeutic effect as untreated platelet doses.

[3] AABB Bulletin No. 21-02 at 5 (June 2, 2021, https://www.aabb.org/docs/default-source/default-document-library/resources/association-bulletins/ab21-02.pdf?sfvrsn=6c304e60_0).

68. All PRT processed platelets must be transfused within five days of collection or they expire ("5-day platelets"). A recently published clinical study concluded that INTERCEPT-treated platelets did not meet the long-established FDA criterion for extending platelet storage to seven days.

69. On a per-dose basis, PRT is the most expensive platelet bacteria mitigation service. ARC charges $150 per dose for this service.

70. PRT has been associated with two transfusion-related deaths from sepsis caused by bacterial contamination that the PRT process failed to eliminate.

71. As recently as December 2022, the FDA issued a statement warning hospitals about recent sepsis deaths from transfused PRT platelets that were contaminated with bacteria.

2. Large Volume Delayed Sampling

72. LVDS is a testing process similar to the Primary Culture, but it involves taking a larger volume platelet sample and waiting longer before taking and testing that sample.

73. While a Primary Culture is performed 24 hours after collection, LVDS is performed either 36 hours or 48 hours after collection.

74. The sample taken to perform LVDS results in the loss of approximately 7% of each platelet dose (16ml of each 200–250ml dose).

75. LVDS is performed instead of (not in addition to) a Primary Culture.

76. bioMérieux SA manufacturers the BacT/ALERT microbial identification system, which can be used to perform LVDS.

77. Because LVDS is a test of a platelet sample rather than a treatment applied to the platelet, LVDS does not degrade platelet quality. LVDS-tested platelets have the same quality level and characteristics as untested platelets.

78. LVDS can be performed by itself, or it can be combined with subsequent Secondary Testing.

79. LVDS performed at least 36 hours after collection produces 5-day platelets, but the shelf-life of these platelets can be extended to seven-days ("7-day platelets") with additional Secondary Testing.

80. LVDS performed at least 48 hours after collection can generate 7-day platelets.

81. LVDS costs hospitals about half as much as PRT, or $83 per platelet dose.

3. Secondary Testing

82. Secondary Testing involves sampling and testing untreated platelets for bacterial contamination a second time after they are sold to hospitals. Secondary Testing is performed in addition to either 36-hour LVDS or a Primary Culture.

83. The FDA guidance endorses multiple options for Secondary Testing. A hospital can perform a Secondary Culture, which involves repeating the Primary Culture process at a later date. A hospital can also use a Rapid Test, which tests for the presence of bacteria directly (rather than testing for carbon dioxide as a proxy).

84. bioMérieux's BacT/ALERT microbial identification system can be used to perform a Secondary Culture.

85. A Secondary Culture results in the loss of approximately 7% of a platelet dose and can generate 7-day platelets.

86. Verax sells the FDA-cleared PGD*prime*, which is used to perform a Rapid Test.

87. PGD*prime* takes only three minutes to perform and generates results in about thirty minutes. The Test is performed by hospital transfusion service staff.

88. PGD*prime* is performed on the day of the transfusion and uses only a nominal sample of each platelet dose (0.15ml of each 200–250ml dose).

89. PGD*prime* can generate 7-day platelets.

90. Like LVDS, Secondary Testing does not physically degrade the platelets and therefore has no adverse impact on platelet quality or efficacy.

91. Secondary Testing is the least expensive platelet bacteria mitigation service. PGD*prime* averages only $25 per platelet dose, and it requires a minimal amount of labor and equipment.

92. PGD*prime* has a stellar safety track record. More than 1.6 million PGD tests have been distributed to hospitals, and none has ever been associated with a transfusion-related fatality.

D. The Red Cross Embarks on a Campaign to Monopolize the Market for Platelet Bacteria Mitigation Services.

93. Prior to July 2020, ARC sold platelets that were compatible with multiple different bacteria mitigation services. ARC sold PRT platelets as well as untreated platelets that had been tested with either a Primary Culture or LVDS.

94. This gave ARC's platelet customers options in terms of which platelet bacteria mitigation service they purchased and whom they purchased it from. A hospital could buy PRT platelets from ARC, and thereby purchase both its platelet product and its platelet bacteria mitigation service directly from ARC. But a hospital could also buy lower-cost untreated platelets from ARC and then purchase its platelet bacteria mitigation service elsewhere in the form of a Secondary Culture or Rapid Test.

95. Each hospital could choose the platelet bacteria mitigation service or services that worked best for its particular circumstances and patients.

96. This all changed in July 2020, when ARC decided to weaponize its dominant position in the U.S. platelet market to monopolize the U.S. platelet bacteria mitigation services market. To accomplish this goal, ARC started engaging in several forms of illegal conduct,

including tying, exclusive dealing, unfair competitive practices, defamation, and tortious interference.

97. In July 2020, ARC publicly announced that it was implementing a policy of performing the PRT platelet bacteria mitigation service on all of the platelets it sold and would stop selling traditional untreated platelets entirely. ARC announced it would phase in this policy over a period of several years, first by phasing out its sales of Primary Cultured platelets and second by phasing out its sales of LVDS-treated platelets.

98. Once ARC's policy is fully implemented, ARC's platelet customers would be required to buy only one type of platelet bacteria mitigation service, PRT, and would be required to buy that service only from ARC. ARC's platelet customers would no longer have any choice over what type of platelet bacteria mitigation service to buy or whom to buy it from.

99. And ARC announced it would charge an eye-watering $150 *per dose* for this service. This is more than 30% of the price of the platelets themselves (a platelet dose costs approximately $462).

100. ARC warned its customers to immediately start preparing to receive all of their platelet bacteria mitigation services solely from ARC and solely on ARC's terms.

101. Because the U.S. platelet market is severely supplied-constrained (due to chronic donor shortage) and ARC is by far the largest seller (controlling almost half the entire market), hospitals have no choice but to agree to buy their platelet bacteria mitigation services from ARC.

102. In October 2021, ARC stopped selling untreated Primary Culture platelets entirely. This made it impossible for its platelet customers to employ Secondary Testing and to buy their bacteria mitigation services from Verax, or bioMérieux.

103. ARC continues to sell some LVDS platelets today while it continues to ramp-up its PRT processes, but it has announced that its transition to performing PRT on 100% of its platelets will be complete at some point in 2023.

104. Once this transition is complete, ARC's customers will only be able to purchase the PRT bacteria mitigation service and only from ARC itself.

1. Tying

105. ARC's July 2020 policy of applying its platelet bacteria mitigation service to all of its platelets is a classic antitrust tie.

106. Platelets are a good and platelet bacteria mitigation services are a service. They have separate markets.

107. Historically, ARC sold untreated platelets, and its hospital customers had a choice of where to buy their bacteria mitigation services. They could buy the PRT or LVDS services directly from ARC, or they could buy Secondary Testing services from Verax or bioMérieux.

108. ARC's July 2020 policy tied its sales of platelets to its sales of platelet bacteria mitigation services.

109. Under this policy, ARC's platelet customers are required to buy their platelet bacteria mitigation services from ARC as well. Customers are thereby deprived of the option of buying that service from Verax or another one of ARC's competitors.

110. ARC's customers are being forced to buy only one type of platelet bacteria mitigation service—PRT—and to buy that service solely from ARC itself.

111. ARC intends to fully implement its policy by 2023.

112. By requiring its customers to purchase its platelet bacteria mitigation services along with its platelets, ARC is leveraging its dominance in the U.S. platelet market to monopolize the U.S. platelet bacteria mitigation services market.

113. ARC's tying arrangement forecloses other sellers of platelet bacteria mitigation services, such as Verax, from selling to ARC's platelet customers, which are the vast majority of potential buyers of platelet bacteria mitigation services. This improperly prevents Verax and other sellers of platelet bacteria mitigation services from freely competing in the market.

2. Exclusive Dealing

114. On information and belief, to further its goal of monopolizing the market for platelet bacteria mitigation services, ARC executed an exclusive dealing contract with Cerus Corporation in which ARC agreed to buy exclusively Cerus's INTERCEPT treatment technology and provide exclusively INTERCEPT-treated PRT platelets to hospitals.

115. This exclusive arrangement enabled ARC to preclude hospitals from using any platelet bacteria mitigation service other than PRT or from buying that service from anyone other than ARC.

116. This has foreclosed a substantial amount of the U.S. market for platelet bacteria mitigation services.

117. ARC is also pursuing a policy of *de facto* exclusive dealing arrangements with its U.S. platelet customers. Whereas ARC's customers used to be able to buy some or all of their platelet bacteria mitigation services from Verax or another provider of such services, under ARC's July 2020 policy these customers are now required to buy all of those services exclusively from ARC itself.

118. Because ARC has a dominant position in the platelet market (and other blood products markets that hospitals rely upon), hospitals cannot afford to forego access to ARC's platelets and therefore have no choice but to acquiesce to *de facto* exclusive dealing contracts for platelet bacteria mitigation services. Purchasers have likewise lost the ability to *threaten* to acquire

platelet bacteria mitigation services from other suppliers, removing a key form of discipline on pricing.

119. By coercing its customers into exclusive contracts, ARC is excluding its competitors from a substantial portion of the platelet bacteria mitigation services market.

3. Unfair Trade Practices, Defamation, and Tortious Interference

120. In addition to its anticompetitive practices, ARC is also engaging in defamation, unfair and deceptive trade practices, and tortious interference.

121. ARC has defamed Verax and its PGD*prime* test by making false and defamatory statements about PGD*prime* publicly and to Verax's customers.

122. For example, in July 2020, ARC sent hospitals that purchased PGD*prime* a document entitled, "The American Red Cross Approach to Platelet Safety, *Implementation Plan for Bacterial Control Strategies*, Frequently Asked Questions" ("FAQ"). It also published this FAQ publicly on its website.

123. This FAQ falsely disparaged PGD*prime* in numerous ways and sought to instill in Verax's customers the false and damaging belief that PGD*prime* is costly, unsafe, and ineffective.

124. The FAQ asserts that "secondary, point-of-issue (POI), bacterial testing (e.g., the Verax PGD test) involves a new testing regimen for most hospitals, is time consuming to perform and involves significant cost both in materials and staff time." This assertion is objectively false and defamatory because PGD*prime* is the *least* expensive bacteria mitigation service, and therefore saves hospitals money compared to PRT. Upon information and belief, ARC issued this statement knowing it was false and/or misleading (or, at minimum, issued it with reckless disregard for whether its statement was true and/or non-misleading) with the intent of undermining and harming Verax's customer relationships.

125. The FAQ also asserts that "PR platelets offer the best and most efficacious approach to ensuring platelet safety while sustaining the blood supply." This statement is objectively false and deceptive because there is no empirical basis for the claim that PRT has superior efficacy to PGD*prime* or other Secondary Testing. To the contrary, trials have established that PRT degrades platelet quality, resulting in an overall need for more and more frequent platelet transfusions for some patients. And the FDA has reported two sepsis fatalities associated with PRT, while no such cases have ever been associated with *PGDprime*. Again, upon information and belief, ARC issued this statement knowing it was false and/or misleading (or, at minimum, issued it with reckless disregard for whether its statement was true and/or non-misleading) with the intent of undermining and harming Verax's customer relationships.

126. The FAQ also asserts that platelets become "dysfunctional" if stored longer than five days and that providing platelets compatible with Verax's test would "add additional costs and inventory management complexity potentially compromising the platelet supply." This statement is deceptive because the FDA has recognized no efficacy benefit to transfusing platelets within five days of collection rather than within seven days. This statement is further deceptive, false, and defamatory because Verax's test objectively reduces costs and inventory management complexity compared to PRT treatment. ARC issued this statement knowing it was false and/or misleading (or, at minimum, issued it with reckless disregard for whether its statement was true and/or non-misleading) with the intent of undermining and harming Verax's customer relationships.

127. The FAQ also asserts that ARC's decision to sell only PRT platelets was made to "protect the safety and availability of the platelet supply." This statement is deceptive because ARC's decision to sell only PRT platelets has no positive impact on safety or the availability of

platelet supply. To the contrary, ARC decision increases the number of transfusions, which adds safety risks (every additional transfusion carries multiple non-infectious safety risks) and strains the supply of platelets, making platelets more expensive and less available. Upon information and belief, ARC issued this statement knowing it was false and/or misleading (or, at minimum, issued it with reckless disregard for whether its statement was true and/or non-misleading) with the intent of undermining and harming Verax's customer relationships.

128. The FAQ also asserts that "[p]athogen reduction contributes to a stronger blood supply by qualifying more units for transfusion through the elimination of false positives associated with aerobic and anaerobic culturing and rapid testing." This statement is objectively false because Verax's PGD*prime* is the only FDA-cleared Rapid Test, and it has not been associated with any false positive results. This statement is defamatory because it falsely suggests that Verax's test generates more platelet waste than PRT. Upon information and belief, ARC issued this statement knowing it was false and/or misleading (or, at minimum, issued it with reckless disregard for whether its statement was true and/or non-misleading) with the intent of undermining and harming Verax's customer relationships.

129. The FAQ also asserts that "[p]athogen reduced platelets also offer substantial patient safety benefits and improved inventory simplification." This statement is deceptive because the FDA has recognized no such benefit of PRT, and no clinical trial has established that PRT has any safety benefits compared to Secondary Testing. This statement is objectively false and defamatory because PRT does not provide substantial patient safety benefits compared to Rapid Testing. Upon information and belief, ARC issued this statement knowing it was false and/or misleading (or, at minimum, issued it with reckless disregard for whether its statement was

true and/or non-misleading) with the intent of undermining and harming Verax's customer relationships.

130. Similarly, ARC published defamatory statements about Verax in its Winter 2020 quarterly newsletter, which is distributed to hospitals (including Verax's customers) and published on ARC's website. This newsletter stated that "[p]erformance of secondary culture or rapid testing (e.g., Verax testing) adds additional labor, cost to the transfusion service, and reduces the final product volume." This statement is objectively false and defamatory because PGD*prime* reduces, not increases, the cost of transfusions. This statement is further objectively false and defamatory because *PGDprime* does not result in a reduction in final product volume compared to PRT or LVDS. Upon information and belief, ARC issued this statement knowing it was false and/or misleading (or, at minimum, issued it with reckless disregard for whether its statement was true and/or non-misleading) with the intent of undermining and harming Verax's customer relationships.

131. In August 2020, Verax contacted ARC regarding the false, defamatory, deceptive, and misleading statements it made in its FAQ.

132. In response to Verax's letter, ARC revised its FAQ to remove some, but not all, of its false, defamatory, and misleading statements. ARC never issued a correction.

133. Upon information and belief, ARC continues to repeat these types of false, defamatory, and misleading statements to Verax's past, current, and prospective customers with the intent of undermining and interfering with Verax's customer relationships.

134. Prior to discontinuing sales of Primary Cultured platelets entirely in October 2021, ARC engaged in other deceptive and unfair trade practice as well, all with the goal of tortuously interfering with Verax's business relationships with its current and prospective customers.

135. Between 2015 and October 2021, ARC falsely told Verax's existing and potential customers that they could not extend the shelf-life of untreated platelets sold by ARC from five days to seven days using Verax's PGD*prime* Rapid Test. This was objectively not true. Upon information and belief, ARC knowingly made these false and/or misleading statements (or, at minimum, made them with reckless disregard to whether they were true and/or non-misleading) to interfere with Verax's current and prospective business relationships as part of ARC's broader effort to monopolize the U.S. platelet bacteria mitigation services market.

136. Upon information and belief, between 2015 and October 2021, when trying to convince Verax's customers to switch to its PRT service, ARC misleadingly told those customers that PRT broadly qualifies for Medicare/Medicaid reimbursement, implying that PGD*prime* did not. In fact, both PRT and PGD*prime* qualify for reimbursement under the exact same circumstances: only in the outpatient setting (approximately 20% of transfusions). ARC's statements were deceptive because they purposefully and falsely implied that ARC's PRT service qualifies for reimbursement more often and more broadly than Verax's PGD*prime* does, and falsely suggested to Verax's customers that they could save money (via reimbursement) by switching from PGD*prime* to PRT. Upon information and belief, ARC knowingly made these false and/or misleading statements (or, at minimum, with reckless disregard to whether its statements were true and/or non-misleading) to interfere with Verax's current and prospective business relationships as part of ARC's broader effort to monopolize the U.S. platelet bacteria mitigation services market.

137. Collectively, these unfair and deceptive trade practices by ARC were intended to harm competition in the U.S. platelet bacteria mitigation services market by interfering with

Verax's customer relationships and driving Verax out of that market so that ARC could achieve monopoly power and sell its service at supracompetitive prices.

E. The Red Cross's Illegal Behavior Outrages the Medical Community.

138. ARC's July 2020 announcement was met with a swift and passionate backlash from the medical community. Hospitals, academics, and doctors all decried ARC's campaign to eliminate competition and choice in the market for platelet bacteria mitigation services.

139. Hospitals (the consumers) in particular are unhappy that ARC is requiring them to buy its PRT service, especially since that service is expensive, can result in the need for additional transfusions, and has been associated with transfusion-related sepsis and death.

140. A group of medical experts from top universities and medical schools sent a letter to the FDA expressing their concern that ARC's policy will adversely affect patients and hospitals. The experts who signed the letter include faculty from Duke University Medical Center, John Hopkins University, George Washington University, Harvard Medical School, University of Nebraska Medical Center, University of Minnesota Medical School, University of Washington Medical Center, University of Pennsylvania Perelman School of Medicine, Dartmouth-Hitchcock Medical Center, and David Geffen School of Medicine at UCLA.

141. These experts complained that because of ARC's tying policy, "hospitals are ultimately being forced to adopt one strategy, PR platelets," resulting in "a risk of leaving hospitals without sufficient platelet inventory or viable options to meet patients' transfusion needs." They also expressed concerns about the efficacy and unjustifiably high cost of PRT compared to LVDS and Secondary Testing.

142. These experts emphasized the importance of consumer choice, which ARC's tying policy and anticompetitive behavior is undermining, if not eliminating entirely.

143. The AABB also issued guidance contradicting ARC's policy of requiring all hospitals to buy only its PRT platelet bacteria mitigation service. The AABB recommends that hospitals purchase multiple different platelet bacteria mitigation services and always be prepared to perform Secondary Testing as a backstop.

144. According to the AABB, the flexibility inherent in employing multiple different platelet bacteria mitigation services is particularly important in the wake of COVID, which reduced platelet donations and created an acute national platelet shortage.

145. ARC's conduct makes it impossible for hospitals to adopt this recommendation.

146. Multiple members of congress have written to the FDA expressing concern that ARC's July 2020 tying policy is increasing prices and eliminating consumer choice.

147. In the face of all this concern and criticism, ARC remains intransigent. ARC continues to aggressively pursue its goal of achieving a monopoly in the market for platelet bacteria mitigation services through tying, *de facto* exclusive dealing, tortious interference, and a variety of unfair and deceptive trade practices.

F. ARC's Illegal and Anticompetitive Conducts Harms Consumers in Numerous Ways.

148. ARC illegal activities and increasing domination of the U.S. platelet bacteria mitigation services market harms consumers in numerous ways. It reduces platelet quality, increases safety risks, prevents the extension of platelet shelf-life, increases costs, eliminates consumer choice, and impedes innovation.

1. Decreased Quality

149. The PRT process physically changes and degrades platelets, resulting in lower transfusion efficacy.

150. PRT platelet transfusions overall result in fewer additional platelets in patients' blood, and patients receiving PRT platelets typically exhibit lower platelet count increments following transfusions compared to patients receiving untreated platelets.

151. Patients receiving PRT platelets overall require more and more frequent transfusions compared to patients receiving untreated platelets. In one clinical trial, patients receiving INTERCEPT-treated platelets required 54% more platelet transfusions and 23% more red blood cell transfusions than patients who received untreated platelets.

152. Lower platelet efficacy can have a particularly large impact on cancer patients and other groups who require recurring platelet transfusions.

153. By forcing all hospitals to switch to using PRT platelets, ARC is decreasing the average quality of platelets and the average efficacy of platelet transfusions.

2. Increased Safety Risks

154. No transfusion is completely safe, and all transfusions carry a risk of adverse health events, such as allergic reactions, fever, bleeding, and sepsis.

155. ARC's policy of selling only PRT platelets increases the overall number of transfusions that patients need, intrinsically increasing those patients' overall safety risks because every transfusion exposes the patient to potential adverse events..

156. Cancer patients and other immunocompromised groups who require recurring platelet transfusions bear the brunt of these increased safety risks and decreased health outcomes.

157. FDA has also reported two septic deaths related to PRT.

158. In its most recent update on this investigation, the FDA explained that the bacteria contamination that caused these deaths occurred *prior* to the PRT process. This means that the PRT process was not effective and failed to eliminate the bacteria in the platelet doses.

159. As a result of these deaths, the FDA has warned hospitals to monitor patients receiving PRT platelets because the PRT process may not eliminate all bacterial contamination.

3. Decreased Shelf-Life and Increased Waste

160. Platelet waste is a substantial and chronic problem in the United States. Because platelets have such a short shelf life, approximately 11% of the donated platelets expire at hospitals before they can be transfused. That amounts to approximately 225,000 doses per year.

161. 48-hour LVDS and Secondary Testing can generate 7-day platelets, while PRT and ARC's 36-hour LVDS can only generate 5-day platelets.

162. 5-day platelets are associated with significantly more platelet waste than 7-day platelets. As a result, ARC's tying policy is exacerbating the ongoing national platelet shortage.

163. In one national survey, hospitals that began employing Secondary Testing reduced their platelet waste from discards by an average of 74%, resulting in an average annual hospital cost savings of $177,000.

164. By forcing all of its hospital customers to use exclusively its PRT platelet bacteria mitigation service, ARC is reducing the shelf-life of those hospitals' platelets by 40%.

165. ARC's policy also requires its customers to buy more platelets because they have to replace the doses that expire. This increases hospital costs and inventory management burdens. It also makes it more likely that a patient will have to delay or forego a platelet transfusion due to lack of supply.

166. ARC's policy forces hospitals to make the Hobbesian choice between maintaining an inventory of platelets that routinely generates waste and being unprepared for major accidents or disasters that require a large number of platelet transfusions in a short amount of time.

4. Increased Price and Costs

167. On a per-dose basis, PRT is by far the most expensive platelet bacteria mitigation service. At $150 per dose, PRT is almost twice as expensive as LVDS and *six times* as expensive as Verax's Rapid Test.

168. As a direct result of ARC's tying policy, the price of platelet bacteria mitigation services has increased significantly, along with the overall price of platelet transfusions.

169. ARC's tying policy also raises consumers' indirect costs.

170. First, because PRT platelets expire more often than untreated platelets, hospitals that purchase PRT platelets have to purchase more platelet doses to cover the same number of transfusions compared to untreated platelets. By forcing all of its customers to buy only PRT platelets, ARC is increasing the overall number of platelet doses and platelet bacterial mitigation services that its customers must buy to perform the same number of transfusions.

171. Second, because PRT platelets are less effective and result in more transfusions on average compared to untreated platelets, ARC's tying policy results in an overall increase in the number of required transfusions. Hospitals need to purchase more platelet doses (and additional labor) to cover these additional transfusions.

172. Thus, ARC's tying policy increases both the direct price of platelet bacteria mitigation services and also the overall cost of providing platelet transfusions.

173. These additional costs are ultimately passed on to patients in the form of higher medical costs and insurance premiums.

5. Loss of Consumer Choice

174. Prior to July 2020, each hospital could choose whichever platelet bacteria mitigation service worked best for its unique situation and patient population.

175. Hospitals that wanted a one-step platelet bacteria mitigation service and did not mind the added cost and shorter shelf-life could purchase PRT or LVDS from ARC. And hospitals that wanted a less expensive alternative with a longer shelf life could purchase untreated platelets from ARC and buy their Secondary Testing from Verax or bioMérieux.

176. The AABB encouraged hospitals to accept and use multiple types of platelet bacteria mitigation services and to always maintain the ability to perform Secondary Testing as a backstop.

177. Prior to July 2020, Secondary Testing had a significant share of the U.S. market for platelet bacteria mitigation services. Hospitals valued this option and the freedom to choose the service that worked best for them.

178. ARC's tying policy is now robbing hospitals of this choice. Because ARC is the dominant supplier of platelets, hospitals are essentially required to purchase its—and only its—platelet bacteria mitigation service.

179. Hospitals are being denied the option of platelet bacteria mitigation services that result in lower priced, longer lasting, higher quality platelets.

180. ARC's tying policy runs directly contrary to the AABB's admonishment that no single platelet bacteria mitigation service is likely to meet the needs of all hospitals.

6. Loss of Innovation

181. ARC's illegal and anticompetitive conduct also inhibits innovation in the market for platelet bacteria mitigation services.

182. Prior to ARC's tying policy, several promising new platelet bacteria mitigation services were in development, including cold-storage, cryopreservation, and lyophilization. These new technologies have the potential to greatly extend the shelf life of platelets and may provide other benefits to patients and hospitals as well.

183. But ARC's anticompetitive conduct is impeding—if not completely eliminating—the development of these new platelet bacteria mitigation technologies. By tying its platelet sales to sales of its PRT platelet bacteria mitigation service and by locking customers up in exclusive contracts, ARC is preventing hospitals from purchasing alternative platelet bacteria mitigation services and foreclosing potential competition.

184. By tying its platelet sales to sales of its PRT platelet bacteria mitigation service and by locking customers up in exclusive contracts, ARC is harming innovation. No company is going to develop a new service it knows it won't be able to sell.

185. As a result, ARC's anticompetitive conduct is robbing hospitals and critically ill patients of the benefits of future medical innovations and increased competition.

V. MARKETS AND MARKET POWER

A. Tying Product Market – U.S. Blood Platelets Market

186. Platelets are a distinct and separate product from other blood components.

187. Platelets, red blood cells, plasma, and other blood components have different collection methods and storage requirements, and they are transfused for different medical purposes. There is no substitute for a platelet when a patient has a clinical need for a platelet.

188. Treated and untreated platelets are substitutes and are all part of the same U.S. platelet market. PRT platelets are simply platelets on which a platelet bacteria mitigation service has already been performed.

189. A hospital that purchase PRT platelets can easily and quickly switch to purchasing untreated platelets and Secondary Testing or vice versa.

190. The relevant overall geographic market for platelets is the continental United States.

191. However, due to their short shelf-life, the vast majority of platelets are sold regionally. As a result, a hospital is generally restricted to buying its platelets from blood centers in the same region.

192. Due to the cost, time, regulatory hurdles, and logistics involved in transporting platelets across borders and oceans, platelets donated outside the continental United States are not feasible substitutes for U.S. platelets. Because of the short shelf-life of platelets, even a day or two of transportation (let alone the time required to clear customs) is not feasible.

B. Tied Product Market – U.S. Platelet Bacteria Mitigation Services Market

193. Platelet bacteria mitigation services is a distinct product market, separate from the markets for bacteria mitigation services for other biological products.

194. Platelets and platelet bacterial mitigation services are distinct products with distinct markets.

195. Platelets are goods, while platelet bacteria mitigation services are services.

196. It is technically feasible (in an emergency situation) to transfuse platelets without the use of any platelet bacteria mitigation service. In fact, this was the standard approach prior to 2004.

197. Historically, platelets and platelet bacteria mitigation services have been sold separately, often by different companies. For example, many hospitals used to buy their platelets from ARC and their platelet bacteria mitigation services from Verax.

198. PRT platelets are not a single product. They are a combination of a good (the untreated platelet) and a service (the platelet bacteria mitigation service). ARC collects untreated platelets from donors and then chooses to perform its PRT service on them.

199. The separateness of platelets and platelet bacteria mitigation services is evidenced by the fact that ARC publicly stated that it was charging a separate and additional $150 per dose

specifically for its PRT platelet bacteria mitigation service (and that it was charging a separate and additional $84 per dose for its LVDS platelet bacteria mitigation service while it ramped up its PRT service).

200. There is no technological, functional, or practical impediment to ARC selling its platelets and platelet bacteria mitigation services separately: ARC could sell untreated platelets to customers who want to purchase Secondary Testing, and it could perform PRT (or LVDS) on platelets for customers who want to buy both the platelets and the platelet bacteria mitigation service from ARC. In fact, ARC did exactly this from 2015 and 2021.

201. Prior to 2021, hospitals routinely purchased their platelets and platelet bacteria mitigation services separately and from different sellers. Between 2015 and 2021, when all of the bacterial mitigation service options were available and hospitals were free to choose, Secondary Testing was the dominant platelet bacteria mitigation service.

202. Within the market for platelet bacteria mitigation services, hospitals and the FDA view PRT, LVDS, and Secondary Testing as substitutes.

203. The relevant geographic market for platelet bacteria mitigation services is the United States.

204. ARC, Verax, and bioMérieux all offer their platelet bacteria mitigation services throughout the entire United States, and any hospital in the United States can switch among them.

205. In contrast, foreign sellers of platelet bacteria mitigation services cannot feasibly sell their services in the United States because of regulatory and logistical hurdles.

206. U.S. hospitals will not purchase (and cannot use) foreign platelet bacteria mitigation services because they are not approved by the FDA.

207. Likewise, FDA approval and other regulatory testing and monitoring requirements prevent foreign platelet bacteria mitigation service providers from entering the U.S. market.

208. Thus, foreign platelet bacteria mitigation services are not a feasible substitute for U.S. platelet bacteria mitigation services.

C. ARC Has Market Power in the U.S. Platelet Market

209. ARC is the largest provider of platelets in the United States.

210. Upon information and belief, ARC sells approximately 50% of all platelets in the United States and a larger percentage in many regions of the country.

211. Upon information and belief, no other seller of platelets has more than approximately 10% share of the U.S. platelet market.

212. While the overall geographic market for platelets is national, blood centers sell the vast majority of their products regionally. The short self-life of platelets often makes it infeasible to transport them long distances, so the vast majority platelets are sold to nearby hospitals.

213. ARC is unique in collecting and selling platelets throughout the entire U.S. market.

214. For example, Vitalant, the second largest blood center, only collects platelets in 20 states.

215. Upon information and belief, in many regions of the country, there are only one or two platelets sellers other than ARC, and in some regions there are effectively no other platelet sellers.

216. Upon information and belief, there are many hospitals that buy 100% of their platelets from ARC.

217. Upon information and belief, the majority of hospitals in the United States buy at least some of their platelets from ARC. Upon information and belief, many of these hospitals

could not replace their ARC platelets with platelets from another seller due to national and regional supply constraints (*i.e.*, platelet donor scarcity).

218. ARC's has a dominant share of the U.S. platelet market.

219. ARC's national market dominance is further enhanced by its unique national footprint and by national and regional platelet supply constraints.

220. Because of its market dominance, ARC can and does set the price of its platelets above the competitive level.

221. ARC's unique national scope—and its competitors' lack thereof—gives it outsized power to raise its prices above the competitive level. Likewise, national and regional platelet supply constraints enhance ARC's ability to raise prices above the competitive level.

222. The limited number of platelet sellers in each U.S. regional market, combined with an extremely inelastic platelet supply, prevents hospitals from foregoing platelets purchases from ARC and purchasing platelets from an alternative blood center instead, even when they believe ARC's policies and terms of sale are draconian.

223. Because of its market dominance, ARC can and does unilaterally impose onerous and/or undesirable terms on its customers, such as the requirement that they purchase all of their platelet bacteria mitigation services from ARC.

224. ARC has also shown its ability and willingness to impede competition through the unfair competitive acts and defamation described above.

D. Significant Barriers to Entry into the U.S. Platelet Market Protect ARC's Market Dominance.

225. ARC's dominant position in the U.S. platelets market is protected by significant barriers to entry, including regulatory hurdles, high fixed costs, and platelet donor scarcity.

226. Platelets are heavily regulated by the FDA's Center for Biologics Evaluation and Research. This regulatory regime requires, among other things, that market entrants register with and receive approval before selling platelets, a process that can take years to complete and cost a significant amount of money. And even after receiving approval, market participants must comply with costly clinical standards, constant reporting requirements, and various monitoring and inspection protocols. This complicated, expensive, and time-consuming regulatory regime deters and delays potential new market entrants.

227. Establishing a regional—let alone national—platelet collection network requires expensive infrastructure with substantial upfront fixed costs, which deters any potential new market entrants.

228. The donation process is uncomfortable, inconvenient, and time-consuming, so new entrants would have great difficulty developing the trust and goodwill necessary to recruit new donors. The limited supply of donors would make it difficult for any new entrant to reach sufficient scale to be profitable.

229. These barriers make any market entry difficult and slow, if feasible at all.

VI. ANTICOMPETITIVE EFFECTS AND ANTITRUST INJURY

230. ARC is engaging in tying, exclusive dealing, unfair competition, defamation, and tortious interference—henceforth referred to as its "Anticompetitive Acts"—with the goal of monopolizing the market for platelet bacteria mitigation services.

A. Injury to Consumers

231. ARC's Anticompetitive Acts restrain and destroy competition in the U.S. platelet bacteria mitigation services market, by unfairly and wrongly depriving ARC's competitors of access to a substantial share of customers in that market.

232. Instead of competing on the merits of price and quality, ARC has decided to condition its sales of platelets (where it has a dominant market position) on the purchase of its platelet bacteria mitigation services, unlawfully tying these goods and services together, and locking a large share of platelet bacteria mitigation service customers into *de facto* exclusive dealing agreements.

233. ARC's Anticompetitive Acts have raised prices, decreased quality, increased waste and administrative burdens, exacerbated an already acute platelet supply shortage, decreased consumer choice, and inhibited innovation. These harms are ongoing.

234. ARC's unlawful tie has independently raised prices, decreased quality, increased waste and administrative burdens, exacerbated an already acute platelet supply shortage, decreased consumer choice, and inhibited innovation. These harms are ongoing.

235. ARC's *de facto* exclusive dealing has independently raised prices, decreased quality, increased waste and administrative burdens, exacerbated an already acute platelet supply shortage, decreased consumer choice, and inhibited innovation. These harms are ongoing.

236. Consumers are materially harmed by each and every one of these effects.

237. These harms will continue and worsen in the future unless ARC's Anticompetitive Acts are enjoined.

238. ARC's Anticompetitive Acts are not justified by any efficiencies or legitimate business considerations.

239. ARC's Anticompetitive Acts insulate it from standard market pressure to reduce price, increase quality, and engage in innovation.

240. But for ARC's Anticompetitive Acts, competition in the U.S. platelet bacteria mitigation services market would be greater.

241. But for ARC's Anticompetitive Acts, barriers to entry into the market for platelet bacteria mitigation services would be lower.

242. But for ARC's Anticompetitive Acts, prices for platelet bacteria mitigation services would be lower and the average quality of those services would be higher.

243. But for ARC's unlawful tie, competition in the U.S. platelet bacteria mitigation services market would be greater, barriers to entry into the market for platelet bacteria mitigation services would be lower, prices for platelet bacteria mitigation services would be lower, and the average quality of those services would be higher.

244. But for ARC's *de facto* exclusive dealing, competition in the U.S. platelet bacteria mitigation services market would be greater, barriers to entry into the market for platelet bacteria mitigation services would be lower, prices for platelet bacteria mitigation services would be lower, and the average quality of those services would be higher.

B. Injury to Verax and Other Market Competitors

245. ARC's Anticompetitive Acts, including its unlawful tie and *de facto* exclusive dealing, have raised competitors' costs in the U.S. platelet bacteria mitigation services market by reducing their actual and potential customer base and by requiring them to engage in wasteful, incremental marketing and related efforts to combat the misinformation published by ARC.

246. As a direct, proximate, and foreseeable result of ARC's violations, Verax is being improperly excluded from a significant portion of the U.S. platelet bacteria mitigation services market, thereby costing Verax customers, sales, and revenues.

247. ARC is using its dominant position in the U.S. platelet market to coerce Verax's former, current, and potential future customers not to buy from Verax, causing Verax to lose sales, revenues, and valuable customer relationships.

248. Customers that would otherwise purchase Verax's PGD*prime* test are effectively prevented from doing so by ARC's tying arrangement regardless of how much those customers prefer PGD*prime* to PRT.

249. Verax's customers have expressly cited ARC's tying policy and exclusive dealing arrangements as the reason for discontinuing or reducing their business with Verax.

C. Need for Judicial Intervention

250. ARC's anticompetitive foreclosure of its competitors' access to customers is restricting competition in the U.S. platelet bacteria mitigation services market.

251. Absent court intervention, this foreclosure and harm to competition will likely continue and worsen in the future.

252. Because ARC controls roughly half of the national platelet supply—which is severely supply-constrained—it is not possible for other platelet sellers to fulfill hospitals' platelet needs if those hospitals tried to forego purchasing platelets from ARC to avoid its tying arrangement.

253. ARC's functional control of the national supply of platelets thereby prevents its customers from avoiding its tying policy and purchasing platelet bacteria mitigation services from other sellers. As a result, market forces cannot defeat ARC's illegal tying policy and court intervention is necessary to restore competition in the market.

254. ARC's Anticompetitive Acts, including its unlawful tie and *de facto* exclusive dealing, also deter and may wholly prevent new entry into the U.S. platelet bacteria mitigation services market. No potential entrant into that market could *also* supply enough platelets in the separate U.S. platelet market to satisfy ARC's current platelet customers' needs.

255. There has been no significant entry into the U.S. platelet bacteria mitigation services market since ARC announced its policy of tying its platelet sales to sales of its platelet bacteria mitigation services. To the contrary, ARC's share of the platelet bacteria mitigation services market has increased dramatically at the expense of its competitors'. No market entry is on the horizon either.

256. Because ARC's Anticompetitive Acts, including its unlawful tie and *de facto* exclusive dealing, cannot be dismantled by natural market forces—either current competitors or potential new market entrants—judicial intervention is necessary to prevent ARC from unlawfully monopolizing the U.S. platelet bacteria mitigation services market and charging supracompetitive prices.

VII. CAUSES OF ACTION

COUNT ONE
(Tying)

257. Verax incorporates and re-alleges each and every allegation contained above as if fully set forth herein.

258. ARC's policy of requiring its platelet customers to buy their platelet bacteria mitigation services solely from ARC satisfies the elements of a tying claim in violation of the Sherman Act.

259. Platelets and platelet bacteria mitigation services are separate products with separate markets. Consumers can buy them together from a single seller or separately from different sellers.

260. The U.S. platelets market and the U.S. platelet bacteria mitigation services market have different sellers, although some entities are sellers in both markets.

261. ARC historically sold platelets separate from platelet bacteria mitigation services, and other entities continue to sell them separately.

262. There is significant consumer demand for untreated platelets, separate and apart from platelet bacteria mitigation services.

263. The tying market is U.S. platelets.

264. ARC is a participant in the U.S. platelet market and has market power in that market.

265. The tied market is U.S. platelet bacteria mitigation services.

266. Both ARC and Verax are participants in the U.S. platelet bacteria mitigation services market.

267. Prior to ARC's tying policy, ARC did not have a dominant share of the U.S. platelet bacteria mitigation services market.

268. ARC has sufficient economic power in the U.S. platelets market (tying market) to force hospitals into purchasing its platelet bacteria mitigation services (tied market) even when those hospitals would prefer to buy that service from another seller. ARC is the largest provider of platelets in the United States, and the scarcity of platelet donors and regional nature of other sellers makes it infeasible that hospitals could satisfy their platelet needs without buying from ARC.

269. ARC's tying arrangement unreasonably restrains trade and is likely to foreclose a substantial amount of the market for platelet bacteria mitigation services from competition.

270. Thus, ARC's tying arrangement is per se anticompetitive and illegal under Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1–2).

271. In addition, ARC's tying arrangement is an unreasonable restraint of trade under the rule of reason in violation of Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1–2) because the restraint has anticompetitive effects that significantly outweigh any procompetitive justifications.

272. By suppressing and foreclosing competition in the market for platelet bacteria mitigation services, ARC's tying arrangement raises prices, reduces quality, increases waste, eliminates customer choice, and impedes innovation. These are all significant anticompetitive effects.

273. ARC's tying arrangement offers no procompetitive benefits, but even if it did, those benefits would not offset the massive anti-competitive effects of the tying policy. Moreover, any procompetitive benefits could be accomplished through the less-restrictive alternative (and its prior practice) of providing customers with the option of purchasing both PRT and Primary Cultured platelets.

274. ARC's illegal foreclosure of free competition and consumer choice has directly and foreseeably harmed Verax by denying it sales and customers it otherwise would have won through fair market competition.

275. Pursuant to 15 U.S.C. §15, Verax is entitled to treble the damages proven at trial and to an injunction prohibiting ARC from tying its sales of platelets to sales of its platelet bacteria mitigation services.

COUNT TWO
(Exclusive Dealing)

276. Verax incorporates and re-alleges each and every allegation contained above as if fully set forth herein.

277. ARC has engaged in a series of exclusive dealing arrangements that unreasonably restrain trade.

278. Upon information and belief, ARC has an exclusive dealing contract with Cerus Corporation under which ARC agrees to buy and use only Cerus INTERCEPT products to perform PRT on its platelets.

279. This exclusive dealing contract enables ARC to tie its platelet sales to sales of its platelet bacteria mitigation service, thereby foreclosing a substantial share of the platelet bacteria mitigation services market.

280. In addition, there are many hospitals that buy all of their platelets from ARC under agreements that are *de facto* (if not expressly) exclusive. Due to ARC's tying policy, these hospitals and other platelet customers are now being forced into *de facto* exclusive dealing contracts with ARC for ARC's platelet bacteria mitigation services as well. Because of ARC's market dominance in the U.S. platelet market, the short shelf-life of platelets, and the acute scarcity of platelet donors, ARC's platelet customers cannot substitute away from ARC to other platelet sellers. As a result, ARC's platelet customers are required to accept ARC's demand that they buy their platelet bacteria mitigation services exclusively from ARC as well.

281. These *de facto* exclusive dealing agreements are inherently coercive to the platelet customers and they foreclose a substantial share of the platelet bacteria mitigation services market.

282. These *de facto* exclusive dealing agreements have no procompetitive benefits. To the contrary, they directly harm platelet consumers by forcing them to pay supracompetitive prices for less effective platelet bacteria mitigation services that generate platelets with shorter shelf-lives.

283. ARCs exclusive dealing arrangements violate Sections 1 and 2 of the Sherman Act (15 U.S.C. §§ 1–2).

284. As a direct, proximate, and foreseeable result of ARC's exclusive dealing arrangements, Verax has suffered and continues to suffer substantial economic harm in the form of lost sales and revenues.

285. Pursuant to 15 U.S.C. §15, Verax is entitled to treble the damages proven at trial and to an injunction prohibiting ARC from requiring its platelet customers to buy all of their platelet bacteria mitigation services from ARC.

COUNT THREE
(Attempted Monopolization of U.S. Market for Platelet Bacteria Mitigation Services)

286. Verax incorporates and re-alleges each and every allegation contained above as if fully set forth herein.

287. The U.S. platelets market is a relevant and distinct antitrust market, and ARC has monopoly power in this market.

288. The U.S. platelet bacteria mitigation services market is a relevant and distinct antitrust market, and ARC and Verax both participate in this market.

289. ARC is now requiring its platelet customers to also purchase its PRT platelet bacteria mitigation service.

290. ARC's platelets and PRT service are separate and distinct products. ARC previously offered untreated platelets separate from its PRT service, and other blood centers still sell these products separately.

291. There is significant consumer demand for platelets separate and apart from platelet bacteria mitigation services. Many hospitals want to use platelet bacteria mitigation services other than PRT to reduce cost and extend platelet shelf life.

292. ARC has sufficient economic power in the U.S. platelet market to coerce hospitals into purchasing platelet bacteria mitigation services from ARC that they do not want. This economic power is enhanced by the short shelf-life of platelets and the acute scarcity of platelet donors.

293. ARC has initiated a policy of tying its sales of platelets to its sales of PRT platelet bacteria mitigation service. ARC has announced a policy of refusing to sell platelets separate from its platelet bacteria mitigation service.

294. ARC is requiring the hospitals that buy all of their platelets from ARC into *de facto* exclusive dealing arrangements where they must also buy all of their platelet bacteria mitigation services from ARC.

295. ARC is *de facto* or actually refusing to deal with customers who want to buy platelets from ARC but platelet bacteria mitigation services from another seller, such as Verax.

296. The scarcity of platelet donors; the immense infrastructure required to collect, package, and sell platelets; and the substantial regulatory requirements involved in selling platelets all create significant barriers to entry into the platelet market, which protect ARC's market dominance.

297. These barriers also make it infeasible for most of ARC's platelet customers to avoid ARC's tying policy by foregoing purchasing ARC's platelets and instead buying all of their platelets from other sellers. There is not enough alternative regional platelet supply to meet most hospitals' transfusion needs.

298. ARC's tying and exclusive dealing arrangements do not constitute competition on the merits. The sales and customers ARC gains from such conduct are unrelated to the quality of its product or its business acumen, industry, or skill.

299. ARC has implemented its tying and exclusive dealing arrangements with the intent of monopolizing the U.S. platelet bacteria mitigation services market.

300. ARC's tying and exclusive dealing arrangements have a harmful effect on competition and consumers, which are not outweighed by any procompetitive benefits.

301. There is a dangerous probability that ARC's anticompetitive actions will exclude its competitors from the U.S. platelet bacteria mitigation services market. Even if competitors remain in this market, ARC's market share is likely to rapidly increase as customers shift purchases away from rivals like Verax in order to comply with ARC's tying policy and exclusive dealing arrangements.

302. Because of ARC's tying and exclusive dealing arrangements, there is a dangerous probability that ARC will obtain and unlawfully maintain monopoly power in the U.S. platelet bacteria mitigation services market.

303. ARC's attempt to monopolize the U.S. platelet bacteria mitigation services market violates Section 2 of the Sherman Act (15 U.S.C. § 2).

304. As a direct, proximate, and foreseeable result of ARC's attempt to monopolize the U.S. platelet bacteria mitigation services market, Verax has suffered and continues to suffer substantial economic harm in the form of lost sales and revenues.

305. Pursuant to 15 U.S.C. §15, Verax is entitled to treble the damages proven at trial and to an injunction prohibiting ARC from attempting to monopolize the U.S. platelet bacteria mitigation services market.

COUNT FOUR
(Unfair Methods of Competition and Unfair and Deceptive Practices)

306. Verax incorporates and re-alleges each and every allegation contained above as if fully set forth herein.

307. Verax engages in the conduct of commerce by selling its PGD*prime* test in the U.S. platelet bacteria mitigation services market. Verax sells PGD*prime* primarily from Massachusetts and often to customers in Massachusetts.

308. ARC engages in the conduct of commerce by selling platelets in the U.S. platelet market, including in Massachusetts, and by selling its PRT service in the U.S. platelet bacteria mitigation services market, including in Massachusetts.

309. ARC has engaged and continues to engage in unfair methods of competition and unfair and deceptive practices, including by tying its sales of platelets to sales of its platelet bacteria mitigation services, by attempting to monopolize the market for platelet bacteria mitigation services, by coercing its most reliant platelet customers into exclusive dealing arrangements for its platelet bacteria mitigation services, by defaming Verax, by repeatedly issuing false and misleading statements about its and Verax's platelet bacteria mitigation services, and by tortuously interfering with Verax's customer relationships.

310. ARC has engaged in these unfair methods of competition and unfair and deceptive trade practices in Massachusetts, including by issuing false, defamatory, misleading, and deceptive statements in Massachusetts to Verax's former, current, and prospective Massachusetts customers.

311. These unfair methods of competition violate Massachusetts General Laws 93A Section 2.

312. Verax has been directly, proximately, and foreseeably harmed by ARC's unfair methods of competition.

313. More than thirty days before filing this Complaint, Verax sent a written letter to ARC describing ARC's unfair methods of competition, explaining how those unfair methods are injuring Verax, and demanding that ARC immediately cease these unfair methods.

314. ARC refused to cease its unfair methods of competition and continues to engage in them today.

315. As a result, ARC's violation of Massachusetts General Laws 93A Section 2 is intentional and willful.

316. Verax's principal place of business is within Massachusetts, and Verax sells its PGD*prime* test from Massachusetts and to customers in Massachusetts.

317. ARC does substantial business in Massachusetts, including collecting a substantial amount of platelets in Massachusetts and selling a substantial amount of platelets and platelet bacteria mitigation services to hospitals in Massachusetts.

318. ARC's unfair methods of competition are harming Verax in Massachusetts.

319. The center of gravity of the circumstances giving rise to Verax's unfair methods of competition claim against ARC is primarily and substantially within Massachusetts.

320. Under Massachusetts General Laws Chapter 93A Section 11, Verax is entitled to treble the compensatory damages proven at trial, as well as costs and attorney fees.

COUNT FIVE
(Defamation)

321. Verax incorporates and re-alleges each and every allegation contained above as if fully set forth herein.

322. ARC has publicly stated numerous times and in numerous different ways that Verax's PGD*prime* test is less safe, more expensive, and less effective than ARC's PRT service.

323. These statements are about Verax and its product.

324. These statements are objectively and demonstrably false.

325. These statements are negative and defamatory.

326. ARC made these statements with knowledge of their falsity and/or misleading nature, or with reckless disregard to whether they were true and/or non-misleading.

327. ARC published these false and defamatory statements about Verax with actual malice in order to convince Verax's customers to stop buying Verax's product and to foreclose competition in the U.S. market for platelet bacteria mitigation services.

328. As a direct, proximate, and foreseeable result of ARC's false and defamatory statements, Verax has suffered and continues to suffer substantial economic harm in the form of lost sales and revenues.

COUNT SIX
(Tortious Interference with Contractual Relations)

329. Verax incorporates and re-alleges each and every allegation contained above as if fully set forth herein.

330. Verax had entered into contracts with numerous hospitals to sell them the PGD*prime* test.

331. ARC's tying and exclusive dealing arrangements, as well as its defamatory statements and its unfair and deceptive practices have wrongfully and improperly interfered with Verax's prior, existing, and prospective contracts.

332. ARC intentionally and knowingly engaged in these anticompetitive arrangements and illegal acts for the purpose of interfering with Verax's current and prospective contracts.

333. ARC interfered with Verax's current and prospective contracts with the improper motive of driving Verax out of the U.S. platelet bacteria mitigation services market so that ARC could monopolize that market.

334. ARC's improper interference in Verax's current and prospective contracts harmed Verax by causing it to lose sales and revenues.

VIII. PRAYER FOR RELIEF

WHEREFORE, Verax respectfully requests that this Court enter judgment in its favor, and grant the following relief:

1. Pursuant to 15 U.S.C. § 26, permanent injunctive relief preventing ARC from imposing anticompetitive restraints on the sales of its platelet bacteria mitigation services;

2. Pursuant to 15 U.S.C. § 15, compensatory and treble damages resulting from ARC's violations of the Sherman Act;

3. Compensatory damages resulting from ARC's defamatory statements and tortious interference;

4. Pursuant to Mass. Gen. Laws ch. 93A § 11, compensatory and treble damages resulting from ARC's violations of Massachusetts General Laws Chapter 93A § 2;

5. Pre-judgment and post-judgment interest at the maximum legal rate;

6. Verax's costs, expenses, and reasonable attorneys' fees in bringing this action; and

7. Such other relief as this Court may deem just and proper.

IX. DEMAND FOR JURY TRIAL

Plaintiff Verax requests a jury trial on all matters so triable.

Dated: February 14, 2023

Respectfully Submitted,

By: */s/ Elizabeth K. Keeley*

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